K000620

OCT 3 0 2000

3600 SW 47th Avenue
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662

510(k) SUMMARY

APPLICANT: Medical Device Technologies, Inc.
3600 SW 47th Avenue
Gainesville, FL 32608

CONTACT: Karl Swartz
Quality Assurance Manager

TELEPHONE: (352)338-0440
fax (352)338-0662

TRADE NAMES: PBN Fallopian Tube Catheter System

COMMON NAME: Fallopian Tube Catheter System

CLASSIFICATION NAME: Cannula, Manipulator/Injector, Uterine

SUBSTANTIAL EQUIVALENCE:

Company Name	Product Name	510(k) No.
Cook Urological, Inc.	Rosch-Thurmond Fallopian Catherization Set	K953034

DESCRIPTION OF DEVICE:

The PBN Fallopian Tube Catheter System is comprised of a balloon bearing catheter, a syringe to inflate the balloon, a tungsten tipped catheter, a radiopaque catheter, .018" diameter guidewire, and an .035" diameter guidewire..

The balloon catheter material will be available in 10 Fr. size, and is extruded from a flexible plastic tube, that is 30 to 40 cm in length. The distal end will have an end port. The balloon, which is composed of a synthetic elastomer of a natural, clear kraton material, is mounted 3 to 5 mm proximal to the distal end. The proximal end of the catheter is composed of a Y fitting leading

The syringe is a 5-cc size and has a vent at the 4-cc graduation providing that volume for inflation of the balloon.

The tungsten tipped catheter material will be available in 5 Fr. size and is extruded from a flexible plastic tube, that is 40 to 50 cm in length. The distal end has a tungsten tip for approx. .8 to 1.0 cm.

The radiopaque catheter material will be available in 3 Fr. size and is extruded from a flexible plastic tube, that is 55 to 60 cm in length. The material is layered with nylon, then tungsten/nylon, and nylon.

INDICATIONS FOR USE:

The PBN Fallopian Tube catheter System is intended for selective catheterization/cannulation of the fallopian tubes for injection of dye or contrast medium in order to evaluate proximal tubal occlusion/patency under luoroscopy, ultrasonography, hysteroscopy, or laparoscopy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Karl Swartz
Quality Manager
Medical Device Technologies, Inc.
3600 SW 47th Avenue
GAINESVILLE FL 32608

Re: K000620
PBN Fallopian Tube Catheter System
Dated: July 28, 2000
Received: August 1, 2000
Regulatory class: II
Unclassified/Procode: 85 MOB

Dear Mr. Swartz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

MEDICAL DEVICE TECHNOLOGIES INC
00 SW 47th Avenue
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662

510(k) Number (if known): K000620

Device Name: PBN Fallopian Tube Catheter System

Indications for Use:

The PBN Fallopian Tube catheter System is intended for selective catheterization/cannulation of the fallopian tubes for injection of dye or contrast medium in order to evaluate proximal tubal occlusion/patency under fluoroscopy, ultrasonography, hysteroscopy, or laparoscopy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER ~~PAGE IF NEEDED~~)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-9

David A. Segraves
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000620